DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

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Dear Fish and Fishery Products Industry:

In light of the accident, on April 20, 2010, in which an oil platform in the Gulf of Mexico caught fire and sank, the Food and Drug Administration (FDA) wants to remind fish and fishery product processors of FDA's regulations and policy concerning the food safety hazard of environmental chemical contaminants.

The accident resulted in a large, ongoing release of crude oil into the environment. Environmental chemical contaminants, such as polycyclic aromatic hydrocarbons (PAHs) from crude oil, in fish and shellfish pose a potential human health hazard. These contaminants may accumulate in fish and shellfish at levels that can cause illness.

As is the case with most oil spills off the coast of the United States, state and federal authorities closed waters to fish and shellfish harvesting to prevent the sale or consumption of potentially contaminated fish and fishery products.

FDA's Fish and Fishery Products Regulation (Title 21 of the Code of Federal Regulations Part 123 (21 CFR 123)) requires processors to have and implement a written Hazard Analysis Critical Control Point (HACCP) plan when a hazard analysis reveals that one or more food safety hazards are reasonably likely to occur (21 CFR 123.6(b)). Furthermore, these processors are required to reassess the adequacy of their HACCP plan or, when a processor does not have a HACCP plan because a hazard analysis did not reveal food safety hazards that were reasonably likely to occur, to reassess the adequacy of their hazard analysis whenever any changes occur that could affect the hazard analysis or alter the HACCP plan in any way (21 CFR 123.8(a)(1); 21 CFR 123.8(c)).

The regulation specifically requires processors of molluscan shellfish to include in their HACCP plans how they are controlling the origin of the molluscan shellfish they process to ensure that they only process shellfish harvested from growing waters approved for harvest by a shellfish control authority or, in the case of shellfish harvested from U.S. Federal waters, from waters that have not been closed to harvesting by an agency of the Federal government (21 CFR 123.28). To meet this requirement, processors who receive shellstock must only accept shellstock from a harvester that is in compliance with the licensure requirements that apply to the harvesting of molluscan shellfish or from a processor that is certified by a shellfish control authority, and that has a tag affixed to each container of shellstock.

The tag must include the date and place the shellstock were harvested (by State and site), type and quantity of shellfish harvested, and an identification of the harvester or the harvester's vessel. In place of the tag, bulk shellstock shipments may be accompanied by a bill of lading or similar shipping document that contains the same information (21 CFR 123.28(c); 21 CFR 1240.60(b)).

The regulation does not include specific requirements for other fish and fishery product processors on what to include in their HACCP plans to ensure that they only process fish, and other types of shellfish, from waters that have not been closed to harvesting by state and federal authorities. However, FDA provides recommendations concerning different control strategies that processors may use to control environmental chemical contaminant hazards in Chapter 9 of FDA's "Fish and Fisheries Products Hazards and Controls Guidance - Third Edition; June 2001" (the Guide). One of these control strategies is called "Source Control."

For products other than molluscan shellfish, FDA recommends among other things that processors of fish and fishery products set a critical limit in their HACCP plan of "No fish may be harvested from an area that is closed to commercial fishing by foreign, federal, state, or local authorities" and establish monitoring procedures for the "Location and status (e.g. open, closed) of the harvest area" for "Each lot received" to ensure that the critical limit is consistently met. (See Control Strategy Example 6- Source Controls in Step 14 (Set the critical limits (CL) & Step 15 (Establish monitoring procedures) of Chapter 9 of the Guide).

The Guide also provides recommendations on what corrective actions should be taken if the critical limits are not met, what records to keep, and how to verify that the HACCP plan is adequate to address the hazard and is consistently being followed.

FDA recognizes that the oil spill has had a major impact on much of the fish and fishery products industry in the region. In the coming days, FDA will conduct a conference call with Gulf state stakeholders to review expectations, answer questions, and ensure that processors have plans and tools in place to ensure the safety of the seafood they are receiving and selling to their customers.

Sincerely,

Michael M. Landa
Acting Director
Center for Food Safety
and Applied Nutrition